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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/706,104

11/12/2003

Douglas Craig Scott

9118M

5134

27752 7590 11/06/2009
THE PROCTER & GAMBLE COMPANY
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EXAMINER

GEMBEH, SHIRLEY V

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

11/06/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/706,104	Applicant(s) SCOTT ET AL.	
	Examiner SHIRLEY V. GEMBEH	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-20, 24-29, 31, 32, 34 and 36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-20, 24-29, 31-32, 34 and 36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments and amendments

1. The response filed on 7/10/09 has been entered.
2. Applicant's arguments filed 7/10/09 have been fully considered but they are not deemed to be persuasive.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 18-20, 24-29, 31-32, 34 and 36 are pending in this office action.
5. The rejection of claims 18-20, 24-29 and 31 under 35 U.S.C. 102(e) as being anticipated by Lawlor (US 6,706,256) is withdrawn due to the amendment of the claims and a 103 rejection is made.

Declaration

6. The declaration of Douglas Craig Scott submitted under 37 CFR 1.132 filed 12/9/08 is insufficient to overcome the rejection of claims 18-20, 24-29 and 31 based upon the rejection Lawlor (US 6,706,256 B2) in view of La Rochelle (US 4,157,386) and Aberg et al., (WO 88/10110) as set forth in the last Office action because:

The declaration is not commensurate in scope with the claimed invention. The claims are broader than what is shown as an unexpected result. For example the claims

recite "... composition comprising from about 7% to about 25% by weight of the composition of a retentive agent comprising hydroxyethylcellulose and carboxymethylcellulose..." while the declaration presents data with only 7% hydroxyethyl cellulose and about 4% carboxymethyl cellulose (i.e., only one point data). Therefore, the showing of only one point data is not commensurate in scope because Declarant has not reasonably shown results over the wide range claimed (see claim 18) thus that the unexpected result would be a trend covering the claim subject matter. Additionally, Lawlor teaches "the methods are improved the longer the composition remains in the oral cavity". Additionally, one of ordinary skill in the art would expect that formulating a composition with HEC and CMC would reasonably stay in the oral cavity (on the teeth) for a longer period of time because Lawlor teaches that it is preferred that that the compositions are formulated to encourage the consumer to retain them in the cavity (see col. 24, lines 39-45). Thus the unexpected result is truly not unexpected based on the teaching of Lawlor.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18-20, 24-29, 31-32, 34 and 36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

application was filed, had possession of the claimed invention. This is a New Matter Rejection.

The claims recite the newly amended limitation of "... from about 4% to about 15% hydroxyethyl cellulose and about 3% to about 10% carboxymethylcellulose" (in independent claim 18); and "about 7% hydroxyethylcellulose and about 4% CMC" (in independent claim 28 for example). However, the specification as-filed does not envision (a) a combination of HEC and CMC in the amounts recited in the amended claims; (b) the specification as filed does not envision HEC retentive agent at about 4-15% and 3% to about 10% CMC.

Applicant argues that "...the claimed ranges and amounts are included within the range in the specification and properly supported". Applicant further argues that "...both hydroxyethylcellulose and carboxymethylcellulose are listed on page 8, line 8 of the specification as available retentive agents, including mixtures thereof, page 8, line 12". Applicant further argues that [t]he specification states that the level of the particulate retentive agent may be "from about 1% to about 40%", and "therefore, the claimed ranges and amounts are included within the range".

In response, page 8, line 12 of the specification only recites Markush types of retentive agents and not a combination of specific formulation of HEC and CMC as asserted nor does the specification as filed envision HEC retentive agent at about 4-15% and 3% to about 10% CMC or 7% HEC and 4% CMC as now claimed.

The assertion that "[t]he specification states that the level of the particulate retentive agent may be "from about 1% to about 40%," and "therefore, the claimed ranges and amounts are included within the range" is found not persuasive because 1% to about 40% of the particular retentive is not the same as having the retentives in a specific ratio as 7% of HEC and 4% of CMC.

Contrary to Applicant's assertion, pages 7-8 only disclose the embodiment of 1%-40%, 7%-25%, 8%-20% and 11%-18% of the retentive agent, and fail to show any combination of the individual agents in the concentrations recited by the instant claims.

8. After further consideration a new rejection is under 35 U.S.C. 103(a) as being unpatentable Over Lawlor (US 6,706,256).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 18-20, 24-29, 31-32, 34 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable Over Lawlor (US 6,706,256) in view of La Rochelle, (US 4,157,386). Lawlor teaches an oral care formulation (dentifrice) comprising of hydroxyethyl cellulose (HEC) and water soluble salts of cellulose such as carboxymethyl cellulose (CMC) in the amount of 0.1%-15% (as required by instant claims 18, 28, 32 and 34; see col. 21, lines 45-56) and a flavoring agents, and abrasives (as required by instant claim 18(b); see col. 18, lines 1-10). Intrinsically, buffering and or providing sustained delivery would be apparent when the Lawlor's oral formulation is chewed. Therefore, Lawlor's formulation when chewed is expected to form a hydrated mass that will be visible on 2-3 molars of the teeth or greater for at least 5 mins (as it also relates to claims 18 and 19; see also col. 17, lines 19-32). Lawlor teaches a non-cariogenic composition (see col. 20, lines 43-55) having the same structurally components claimed. Therefore, Lawlor's composition will function the same as the claimed composition (i.e., remain on the tooth for more than 5 mins) absent factual evidence to the contrary. The limitations such as

brushing with a manual flat head, soft tooth brush for 30 seconds expectorates the slurry and rinsing with 10 ml water and expectorate again is recitation of the intended use. It should be noted that the composition must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. In the instance case since Lawlor et al. teach the same composition it must be capable of performing the intended use, therefore, meets the claim intended use as required by instant claims 18-19,20, 28,32 and 34.

Lawlor also teaches the composition comprises additional agents such as H-2 antagonists, anticalculus, fluoride ions (as required by instant claims 24 and 25; see col. 9, lines 59-67) in a compressed tablet (as required by instant claim 26; see col. 15, lines 46-48). With the limitation wherein the composition is non-effervescent, it is anticipated that chewing gum and hard candies are non-effervescent, thus the limitation of instant claims 26-27 and 31 is met. Lawlor further teaches the oral composition comprises a buffering agent wherein the buffering agents have a pH of 3-10. Therefore when chewed the composition will buffer the oral cavity within the recited claimed limitations (as required by instant claims 28-29, see col. 22, lines 1-16).

Lawlor further teaches the oral composition comprises metal cation salts which are water insoluble salts less than 2% of insoluble particulates (i.e., less than 65%; see col. 12, lines 56-60 and col. 14, lines 36-40 as required by instant claim 28).

Applicant should note that "products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the

properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990), "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." See MPEP 2112.01.

However, Lawlor fails to teach the specific combinations of a retentive agent as 4-15% HEC and from about 3-10% CMC (as required by instant claim 18) Nor does Lawlor teach the specific percentages of HEC as 7% and 4% of CMC (as required by instant claims 28, 32, 34 and 36).

Even though Lawlor fails to teach the specific percentages of HEC and CMC (as required by instant claims 18, 24, 32, 34 and 36) based on the teachings of Lawlor, (i.e., the oral care formulation (dentifrice) comprises 0.1%-15% of HEC and CMC), one of ordinary skill in the art would have been motivated to optimize the ratio of HEC and CMC in the composition so that when chewed will form a hydrated mass that will be visible on 2-3 molars or greater for at least 5 mins. Specifically Lawlor teaches that "the methods are improved the longer the composition remains in the oral cavity". Therefore, one of ordinary skill in the art would be motivated to formulate a composition with HEC and CMC that would reasonably stay in the oral cavity (on the teeth) for a longer period of time because Lawlor teaches that it is preferred that that the

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compositions are formulated to encourage the consumer to retain them in the cavity (see col. 24, lines 39-45). Having said that it is therefore reasonable that one of ordinary skill in the art would be motivated to determine the amount of HEC with CMC that shows the optimum therapeutic index to get the maximum effect of the drug, hence the Lawlor makes obvious the instant invention.

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL HARTLEY can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/S. V. G./
Examiner, Art Unit 1618
10/26/09

/Michael G. Hartley/
Supervisory Patent Examiner, Art
Unit 1618